



TS-ONE® Patient's handbook



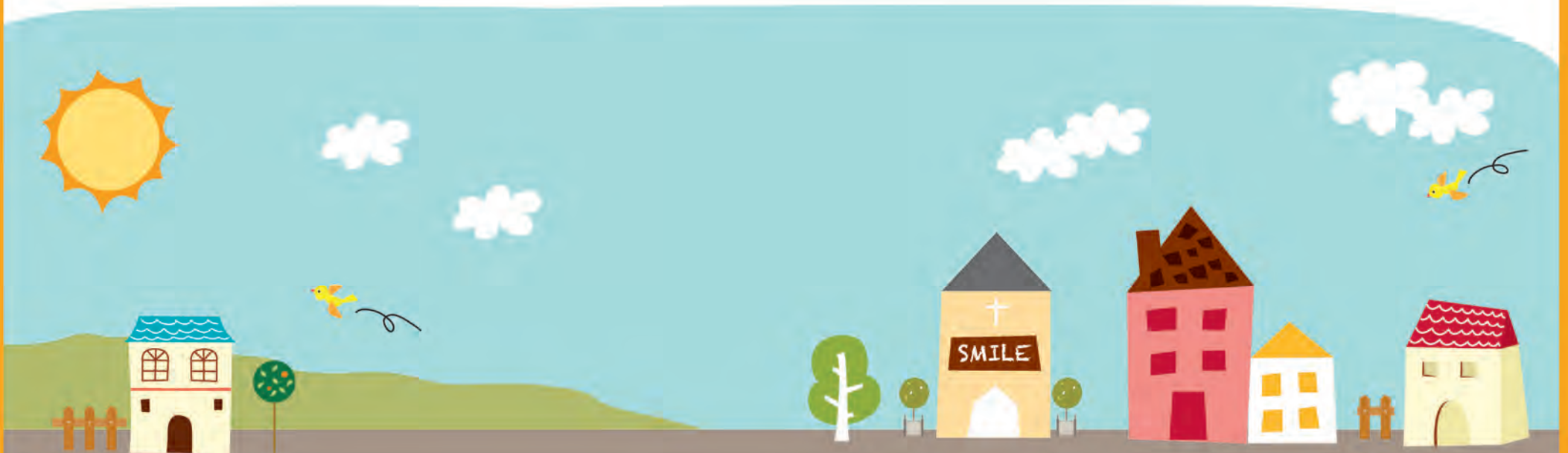
This booklet should be distributed by doctor or health professionals.
Information provided is for reference only and please contact your doctor, pharmacist or nurse for further enquiries.



TAIHO
PHARMA ASIA PACIFIC

Introduction

This booklet contains useful information for people who are going to take TS-ONE®. It is a guide to know TS-ONE® better; includes the most important safety information, dosage information, its effectiveness, common side effects and the ways to deal with them. Please take the time to read through this booklet before starting to take TS-ONE®. If you can't find the information you need, if you have any questions and concerns, please do not hesitate to talk them over with your doctor, pharmacist, or nurse. In addition, a medication log book is attached for you to keep track of your medication schedule and physical conditions.



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What is TS-ONE®?

TS-ONE® is a fluoropyrimidine anticancer drug. It is developed to reduce the adverse drug reactions while enhancing the effectiveness of 5- fluorouracil (5-FU).

TS-ONE® is a combination of three pharmacological compounds below.

Tegafur becomes 5-FU when metabolized.

5-FU can prevent the growth of cancer cells or result in cancer cell death.

Gimeracil inhibits 5-FU degradation, and sustains anti-tumor activity.

Oteracil Potassium reduces digestive side effects such as diarrhea, while reducing toxicity associated with 5-FU.

The most important information you should know

TS-ONE® is an oral drug approved in most Asian regions and European countries. You can take TS-ONE® at home or work not only at hospital. However, please make a regular visit to your doctor to ensure the safety and effectiveness of your medication. Please follow your doctor's instructions.

TS-ONE® 20mg Capsule



Actual size

TS-ONE® 25mg Capsule



Actual size

Please tell your doctor, pharmacist, or nurse before taking TS-ONE® if you:

- Are taking any medicine currently
- Have any allergies to food and medicine
- Have or have had any kidney or liver problems (including abnormal blood test results)
- Are pregnant or possibly being pregnant

The most important information you should know

TS-ONE® should never be taken together with certain medications listed below.

It may cause severe side effects such as mouth sores, diarrhea and leukopenia if you take TS-ONE® together with the medicine below. It may increase the chemicals in your blood extremely.

Never take with : Fluoropyrimidine-Group Drugs

Fluoropyrimidine-group anti-cancer drugs

Fluorouracil (5-FU) | Tegafur / Uracil (UFT)

Tegafur (Futrafur) | Doxifluridine (Furtulon)

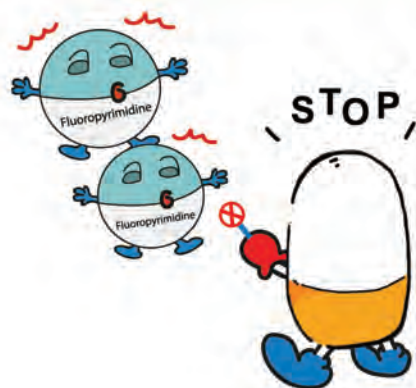
Capecitabine (Xeloda) | Carmofur (mifuror)

Folate plus Tegafur Uracil combination therapy (UZEL/UFT)

Levofolate and fluorouracil combination therapy (Isovorin/5-FU)

Fluoropyrimidine-group anti-fungal agents

Flucytosine (ancotil)



The most important information you should know

Before taking TS-ONE® :

Please tell your doctor or pharmacist about:

- ☉ The medicines you are currently taking, including over-the-counter drugs
- ☉ The old prescriptions and unused medication



☉ Unused medication at home

Never take the unused medication in your house without telling your doctor. If you have any, please consult your doctor or pharmacist before taking any of it

Do not take the unused medication at home



Dosage information and important safety information

Dosage Information

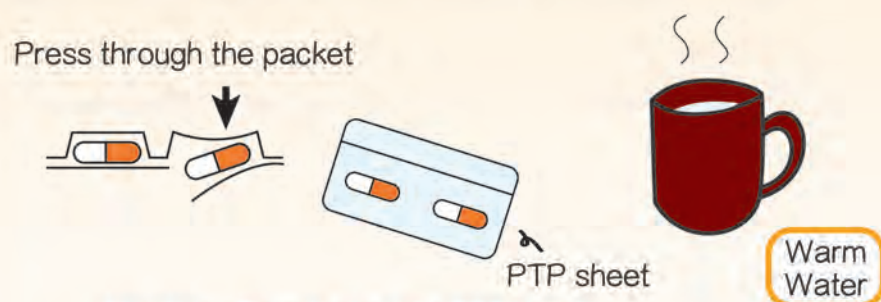
How to take

Take the instructed dose twice daily within 30 minutes after breakfast and the evening meal following your doctor's instruction. Avoid taking on an empty stomach.

The daily dose will be determined upon your height, weight, and physical condition.

TS-ONE® Capsule

Detach a single dose packet from the set of packets. Press through the packet to take out the capsule (PTP sheet). Take with a glass of water or warm water.



Attention : Do not take with PTP sheet

Important Safety Information

(1) Follow the dosage instruction closely

Never change your dose and the dosage schedule on your own.

Your doctor will determine the amount of your dose and the dosage schedule that fit best for your condition. Please do not change them on your own.

Dosage information and important safety information

When you need to make a change in your medication.

Your doctor will determine the amount of dose, the dosage schedule (possibly shorter) and the rest period (possibly longer), considering your condition and the adverse reaction.



(2) TS-ONE® must be taken after a meal

For the best result, you must take TS-ONE® **after a meal**. Please ask your doctor if you can take a dose when you cannot eat anything at all.



(3) Visit your doctor periodically for check-ups

Regular health exams and tests can help check the effectiveness and side effects early. Please visit your doctor periodically following his/her instruction.



Visit your doctor periodically

Dosage information and important safety information

(4) Keep the medication log book

Please keep the medication log book and show it to your doctor or pharmacist at your appointment. Write down the dosage of the day as well as your daily physical condition and anything you notice on your condition.



Medication log book

(5) If you miss a dose

Please skip the one you missed (no dosage) and take the next regular scheduled dose. Never take two doses together to make up the missed one. You may experience stronger side effects. If you are not sure if you miss a dose or not, please do not take the dose just in case. If you take a dose more than you should, please contact your doctor or pharmacist immediately.

Miss a dose!

Take the next regular scheduled dose



Side Effects of TS-ONE®

Just like any other cancer drugs, TS-ONE® can cause side effects. There are two kinds of side effects: the physically recognizable and unrecognizable side effects. For the latter you need a blood test to identify. (Such as low white blood cell count, anemia, low platelet count, liver disorder and so on.)

You may be able to prevent or reduce some of the side effects during the medication if you are aware of and prepare for them. Please read the information about the side effects.

Please read
page 8-17



Blood

1. Low white blood cell count

The white blood cell count may decrease when bone marrow function is suppressed. Low white blood cell count leaves the individual susceptible to infections. Your immune system may not be able to resist infections, such as common cold and pneumonia. Infections may affect the whole body in some cases.

Symptoms that may indicate an infection :

- ☀ A fever higher than 38°C and chills
- ☀ Cough and sore throat
- ☀ Painful urination, bloody urine, frequently urination, sense of residual urine



Side Effects of TS-ONE®

Please check your regular body temperature in order to find the infection as soon as possible. It is hard to find out loss of white blood cells. Please take a blood test occasionally following your doctor's direction.

To prevent the infection :

- ☉ Avoid the crowd when you go outside
- ☉ Wash your hands properly (before eating, *before and after using bathroom, after coming home)
- ☉ Gargle often (after coming home, before eating)
- ☉ Leave your mouth clean (by brushing teeth after eating and before sleep)
- ☉ Leave your body clean (by taking bath or shower)

* To avoid the infection through urinary tract, it is necessary to wash hands both before and after using bathroom.



Side Effects of TS-ONE®

2. Anemia

If you experience symptoms below, please contact your doctor or nurse.

- ☉ Feels cold on hands and feet
- ☉ Looks pale on nails and conjunctiva
- ☉ Looks pale
- ☉ Feeling dizzy or giddy
- ☉ Feeling weak or tired more often than usual
- ☉ Rapid heart rate, shortness of breath



When you become anemia :

- ☉ Move slowly (When you wake up and stand up)
- ☉ Walk slowly to avoid rapid heart rate and shortness of breath
- ☉ Ask your family member to accompany, especially when shopping or driving. Avoid too many activities

Tips for meals :

- ☉ Eat a balanced diet. Chew well when eating
- ☉ Eat various protein-rich foods (such as eggs, fish, shellfish, meat and soy)
- ☉ Eat foods that contain vitamin B12 (such as liver meat and asari clams)

Side Effects of TS-ONE®

3 . Low platelet count

Platelets may decrease when bone marrow function is suppressed. Platelets are cells in the blood that help stop bleeding. Low platelet count can result in easy bruising and an inability to stop bleeding, please consult your doctor or nurse.

Symptoms that may indicate loss of platelets:

- ☉ Internal bleeding (bruising)
- ☉ Bleeding in the mouth (by brushing)
- ☉ Nose bleeding (nasal mucosal bleeding by blowing the nose)

What to do if you start bleeding?

- ☉ Wrap an ice pack in a towel and place over bleed, and lay down
- ☉ Pinch the soft part of your nose just below the bridge
- ☉ Put a cold ice pack on your nose

To prevent bleeding :

- ☉ Avoid activities or sports that have a high risk of causing injury. Stay rested as much as possible
- ☉ If you choose to drink, have only a moderate amount of alcohol
- ☉ Be careful to avoid falls, injuries or blows
- ☉ Don't push too hard when you're trying to have a bowel movement
- ☉ Use a soft-bristled toothbrush. Blow your nose gently
- ☉ Shave carefully
- ☉ Wear loose, comfortable clothing

Side Effects of TS-ONE®

Gastrointestinal

1 . Loss of appetite

TS-ONE® may cause a temporary loss of appetite. To keep up your energy, try to eat your favorite food or anything you can even in small amount. When the loss of appetite continues, please consult your doctor or nurse.

Tips for meals :

- ☉ Choose nutritious and easy-to-eat (soft) food (e.g. soup)
- ☉ Choose the food that is high in protein and easy to eat (e.g. tofu, egg-tofu, yogurt etc.)
- ☉ Change how you serve the dish. Arrange and garnish the dish beautifully to increase your appetite. Create a better eating atmosphere



Side Effects of TS-ONE®

2. Nausea

TS-ONE® may cause nausea. In some case you may experience vomiting.

Wear loose, comfortable clothing. Avoid strong scents (such as flowers and perfume.) Lie down or breathe deeply and slowly when you are feeling nauseated. If you experience strong nausea, or nausea lasts for a long time, please consult your doctor or nurse.



Tips for meals :

- ☉ Avoid the dish that causes food smells, such as deep fried foods, stews, stewed fish, etc
- ☉ Take your time, eat slowly
- ☉ Eat a small amount slowly
- ☉ Let the dish cool down and eat
- ☉ Choose the food easy to eat



Side Effects of TS-ONE®

3. Diarrhea

TS-ONE® may cause diarrhea. If diarrhea persists, it may cause dehydration. Please pay attention to your condition.

If you experience these symptoms, please consult your doctor or nurse.

- ☉ Abdominal pain, loose stool, diarrhea (watery stool)
- ☉ Both of mouth sores and diarrhea occur at the same time within a few days after you start to take TS-ONE® (Extra caution is needed in this condition!)
- ☉ Severe diarrhea
- ☉ Diarrhea persists for a long time
- ☉ Increase of bowel movements (at least 4 times a day more than you normally would)

When diarrhea occurs :

- ☉ Avoid the foods that are high in fiber and fat as well as milk and dairy products
- ☉ Avoid stimulants, such as spicy foods, soda, etc

To prevent dehydration :

- ☉ Drink water *often
- ☉ Replenish electrolytes* with sport drinks and proper meals

* Diarrhea results in losing fluid and electrolytes (sodium and potassium, etc) from the body

Side Effects of TS-ONE®

Tips for meals :

- ☉ Choose foods easy to digest
- ☉ Choose foods and drinks high in potassium (Banana, fruit, juice, etc)
- ☉ Eat small portions of the meal several times a day



4. Mouth Sores

TS-ONE® may damage mucous membrane in the mouth. It causes mouth sores. Symptoms include inflammation, sores, ulcers of mucous membranes and gums inside the cheek (Pain and bleeding associated with cuts and swellings in mucous membrane in the mouth). Please consult your doctor or nurse.



Side Effects of TS-ONE®

To prevent mouth sores :

- ☉ Maintain oral hygiene by brushing teeth thoroughly (Use a toothbrush with a compact head and soft bristles)
- ☉ Keep your mouth moist and avoid dryness by gargling or drinking water occasionally
- ☉ Avoid smoking



If you experience mouth sores :

- ☉ Gargle occasionally with light salt water
- ☉ Ask your doctor to prescribe the pain killer if the pain becomes too strong
- ☉ Avoid stimulants such as hot, spicy, sour and deep fried food
- ☉ Cut the ingredients into small pieces to make the meal easier to eat
- ☉ Choose soft food like congee, egg, and tofu, and make your meals thick rather than watery

Side Effects of TS-ONE®

Skin

1. Hyperpigmentation

The color of your skin, nails and fingertips may turn brown or darker after taking TS-ONE®.



To prevent hyperpigmentation :

- ☀ Stay in the shade. Avoid the strong sunlight coming through the window
- ☀ Wear a hat and long sleeves to avoid the direct sunlight when you go outside



2. Rashes

Rashes may occur when you take TS-ONE®. Redness and rashes on face, neck, hand, feet, back etc. When rashes appear all over the body, along "with or without" itching, please consult your doctor or nurse.

If you experience rash :

- ☀ Avoid clothing materials that cause skin irritations, such as wool and synthetic fibers
- ☀ Choose natural cotton clothing in order not to make the symptom worse



Side Effects of TS-ONE®

Others

1. Interstitial pneumonia

Your lung, especially interstitium may become inflamed, and it may decrease your lung function. Although it may occur in 1 out of 300 patients, it is important to be aware of this side effect.

Symptoms are dry cough without phlegm, difficulty to breath, shortness of breath, fever.

If you have suffered from lung inflammation disease in the past, taken radiation therapy, used to smoke or been smoking large amounts for a long period of time, please consult your doctor or nurse.



2. Watery eyes

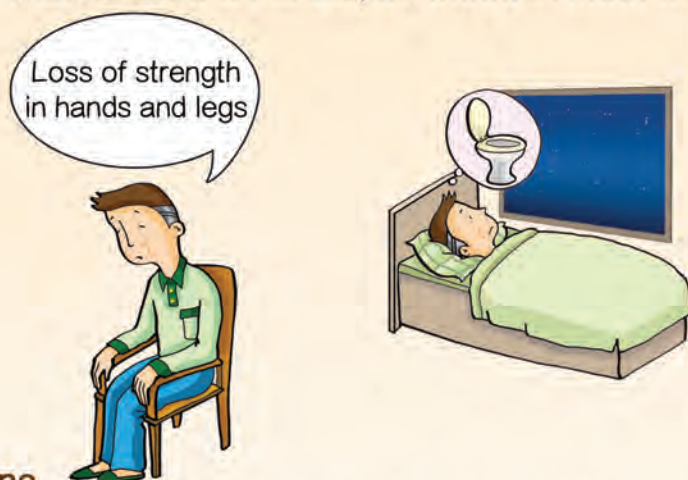
TS-ONE® may affect your tear production. 1 or 2 patients out of 10 may experience this side effect. You may also experience the symptoms like eye redness, blurry, distorted vision, conjunctivitis, keratitis, lacrimal duct obstruction (Blocked tear duct) etc, eye pain and dry eyes. Please consult your doctor or nurse when you notice any problems with your vision.



Side Effects of TS-ONE®

3. Other side effects

Please consult your doctor or nurse if you experience the symptoms like burn-like blisters, palpitation, numbness, muscle pain, decreased urine output, blood in stool etc.



Suggestions

Although the side effects each patient experiences may vary from one to another, it is important for you to know about them in advance. It makes you detect the side effects earlier and to handle them without being worried. The chance, severity and onset time of side effects may vary for each patient, depending on the physical condition. It doesn't mean these side effects would happen to all patients. Please note the condition on your **medication log** and discuss them with your doctor in regular visits.



Questions and Answers

Q1. Do I stop taking the medication if I get a side effect

Answer:

You may need to stop the medication depends on which side effects you are experiencing and how severe they are. Please consult your doctor to decide the time to stop and restart the medication. Monitor your physical condition. To keep taking your medication based on your physical condition is the best way to maximize the effect of the drug.

Q2. Do I take with other anti-cancer drugs together ?

Answer:

You may be administered TS-ONE® with the other anti-cancer drug to increase the effect of the drug. The treatment schedule varies from patient to patient. Please consult your doctor for more details.

Q3. What if it is not my first time to treat cancer ?

Answer:

Telling about your past medical history and experience of the side effects is very important to your doctor when you go for the treatment. Please make sure to tell before starting the medication if you have:

- ☉ Had taken radiotherapy
- ☉ Had taken the other anti-cancer medication
- ☉ Had experienced the side effects

Questions and Answers

Q4. Who should not take TS-ONE®?

Answer:

Some patients may not be able to take TS-ONE® depending on their physical condition. If you think there is a possibility that you can't take TS-ONE®, please consult your doctor beforehand. Your doctor will decide whether you can take TS-ONE® following your blood test results.

Q.5 Can I continue my other ongoing medical treatments?

Answer:

Other medical conditions besides cancer may be worsened with taking TS-ONE®.

Please tell your doctor if you are currently under treatment for or been treated for a medical condition listed below:

Blood, kidney, liver, lung or heart disease, infections, diabetes, stomach ulcer, duodenal ulcer



Questions and Answers

Q.6 Which medicines should not be taken together?

Answer:

You must be aware of accompanying side effects with TS-ONE® if you are taking the medicine below. Please tell your doctor or pharmacist if you think there is a possibility.

Medicine	Effects	Symptoms
Phenytoin (antiepileptic)	Strengthening phenytoin effects	Nausea, nystagmus, dyskinesia
Warfarin potassium (anticoagulant)	Strengthening warfarin potassium effects	Easy bruising, bleeding, gingival bleeding

Q.7 What should I be aware of while taking TS-ONE®?

Answer:



Sleep

Please consult your doctor if you have a problem to sleep



Sport, work, travel

Please listen to your body and rest if you need to



Lifestyle (drinking and smoking)

Please drink only a moderate amount of alcohol, if you choose to. Also quit smoking



Dietary supplements, healthy food products, home remedies

Please consult your doctor or pharmacist before you decide to take

Questions and Answers

Q.8 Can I plan for a baby during my treatment?

Answer:

Studies in animals showed that TS-ONE® can affect the fetus and breast milk. It was reported a woman who used similar anticancer drugs gave a birth to a baby with birth defects. Please use any kind of birth control while taking TS-ONE®.

TS-ONE® may affect men's sperm as well. Please use any kind of birth control while taking TS-ONE®.

Please consult your doctor if you are planning for a baby. (This applies to both men and women.)

Please discontinue breastfeeding while taking TS-ONE®.



Questions and Answers

Q9. How do I store TS-ONE®?

Answer:

- ☀ Please store in a cool, dry place at room temperature. Avoid direct sunlight
- ☀ Please do not let anyone use your medication
- ☀ Please keep away from children



< Medication Log >

(Planned) Dosage Schedule

	SUN	MON	TUE	WED	THUR	FRI	SAT
Date							
Dosage							
Symptoms							
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Dosage							
Symptoms							

Medication

Capsule type

☐ 20mg

One time () capsule x Two Times

When changing is needed
(Month Day)

Capsule type

☐ 20mg

One time () capsule x Two Times

How to write the log:

- Fill the date, the amount of the medication (number of the capsules) you take. If you skip a dose, mark "X" in the box.
(Please do not take double dose to make up the missed one.)
- Circle your appointment day in red. Cross the dates of your rest period.

The medication besides TS-ONE®:

Month	Day~	Month	Day

Month	Day~	Month	Day

Month	Day~	Month	Day

Notes : Please note if you have any concerns.

Symptoms:

Please note the number from the symptom list below, and write it down in the log.

- ① Sore throat
- ② Bleeding (bruising : purple / red)
- ③ Dizziness
- ④ Feeling tired
- ⑤ Numbness, tongue numbness, grogginess, forgetfulness
- ⑥ Shortness of breath, coughing, fever, common-cold like symptom
- ⑦ Nausea, loss of appetite
- ⑧ Diarrhea, abdominal pain, blood in stool
- ⑨ Mouth sore
- ⑩ Inflammation of mucosa membranes in eyes or mouth
- ⑪ Eye irritation, red eyes
- ⑫ Watery eyes, blurred vision, dry eyes
- ⑬ Yellow eyes and skin
- ⑭ Swollen face, hands and feet
- ⑮ Decreased urine output
- ⑯ Loss of sense of smell
- ⑰ Rash, itching, hyperpigmentation, hands and foot dermatitis
- ⑱ Dullness in hand and feet, muscle pain

< Medication Log >

(Planned) Dosage Schedule

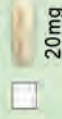
Month Day~ Month Day

(Planned) Dosage Schedule

Month Day~ Month Day

Medication

Capsule type

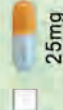


One time () capsule x Two Times

When changing is needed

(____ Month ____ Day)

Capsule type



One time () capsule x Two Times

TS-ONE® medication record

	SUN	MON	TUE	WED	THUR	FRI	SAT
							
							
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Symptoms							
Date							
Dosage							
Symptoms							
Date							
Dosage							

< Medication Log >

(Planned) Dosage Schedule

Month Day~ Month Day

(Planned) Dosage Schedule

Month Day~ Month Day

Medication

Capsule type

☐ 20mg ☐ 25mg

One time () capsule x Two Times

When changing is needed

(___ Month ___ Day)

Capsule type

☐ 20mg ☐ 25mg

One time () capsule x Two Times

TS-ONE® medication record

	SUN	MON	TUE	WED	THUR	FRI	SAT
Date							
Dosage							
Symptoms							
Date							
Dosage							
Symptoms							
Date							
Dosage							
Symptoms							
Date							
Dosage							
Symptoms							
Date							
Dosage							
Symptoms							
Date							
Dosage							
Symptoms							

How to write the log:

- Fill the date, the amount of the medication (number of the capsules) you take. If you skip a dose, mark "X" in the box.
(Please do not take double dose to make up the missed one.)
- Circle your appointment day in red. Cross the dates of your rest period.

The medication besides TS-ONE®:

___ Month ___ Day~ ___ Month ___ Day
 ___ Month ___ Day~ ___ Month ___ Day
 ___ Month ___ Day~ ___ Month ___ Day

Notes : Please note if you have any concerns.

Symptoms:

Please note the number from the symptom list below, and write it down in the log.

- 1 Sore throat
- 2 Bleeding (bruising : purple / red)
- 3 Dizziness
- 4 Feeling tired
- 5 Numbness, tongue numbness, grogginess, forgetfulness
- 6 Shortness of breath, coughing, fever, common-cold like symptom
- 7 Nausea, loss of appetite
- 8 Diarrhea, abdominal pain, blood in stool
- 9 Mouth sore
- 10 Inflammation of mucosa membranes in eyes or mouth
- 11 Eye irritation, red eyes
- 12 Watery eyes, blurred vision, dry eyes
- 13 Yellow eyes and skin
- 14 Swollen face, hands and feet
- 15 Decreased urine output
- 16 Loss of sense of smell
- 17 Rash, itching, hyperpigmentation, hands and foot dermatitis
- 18 Dullness in hand and feet, muscle pain



TAIHO PHARMA ASIA PACIFIC PTE. LTD.
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(the liability of the members is limited)

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